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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,540	03/23/2004	Jorge L. Orbay	HAN-031	2499
36822	7590	08/11/2006	EXAMINER	
GORDON & JACOBSON, P.C. 60 LONG RIDGE ROAD SUITE 407 STAMFORD, CT 06902			SHAFFER, RICHARD R	
			ART UNIT	PAPER NUMBER
			3733	

DATE MAILED: 08/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/806,540

Applicant(s)

ORBAY ET AL. ✓

Examiner

Richard R. Shaffer

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 and 27-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 and 27-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Drawings***

The corrected drawings filed on May 25<sup>th</sup>, 2006 is acknowledged and accepted by the examiner. The previous objections are hereby withdrawn.

### ***Claim Rejections - 35 USC § 112***

The amendment to claim 15 correcting for the reversal of indicated portions is acknowledged. The corresponding rejection has been withdrawn.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10, 19, 20, and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant alleges that the newly added limitations in the independent claim 1 of "an outer surface that defines an outer diameter is at least four times a radial wall thickness of said cap at said engagement portion" and in independent claim 19 of "a wall with a radial wall thickness, an outer diameter at least four times said radial wall thickness" are supported by the specification between Page 5, Line 6 and Page 6, Line 8. However, the specification merely defines the ranges preferred for the outer and inner diameters of the device. With even calculating with an outer diameter of 0.110

Art Unit: 3733

inch (outer diameter of E) and 0.067 inch (inner diameter of F) which would create the thickest radius results in a radial wall thickness of 0.0215 inch. This value means the minimum possible ratio of outer diameter to radial wall thickness ratio being ~5.11.

Applicant clearly in several ways does not have support for "at least 4 times." Further, since the minimum value is ~5.11 and applicant has not stated the benefit of at least 6 times, claim 27 also contains new matter.

Applicant also includes in claims 1 and 19 the limitations directed to pushing is not supported in the specification. Further, there is no support in the specification that states the device the cap is covering is stiff or only a nail.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-7, 11-15, 19, 20, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Simmons et al (US Patent 5,894,110).

Simmons et al disclose a resilient plastic (**Column 2, Lines 63-67**) cap comprising: a cylindrical lead-in portion with a first inner diameter (at **16, Figure 2**); a cylindrical engagement tubular portion (currently arbitrarily from where reference character in **Figure 2** is pointing and up) which is longer than the lead-in portion; the engagement portion defines a second inner diameter (where **18** is pointing, **Figure 2**) smaller than the first inner diameter; the outer diameter of the engagement portion at **18**

Art Unit: 3733

clearly at least 4 times the radial wall thickness at that point; an annular ring (hump at **26**) with a convex outer surface defines a third inner diameter; a fourth inner diameter larger than the third inner diameter and less than the second diameter located just above the hump (**26, Figure 2**); the end (**24**) of the cap (**10**) is closed.

In regard to the limitation of radiopaque, applicant claims a “plastic radiopaque material.” Since in the specification, it clearly is a plastic in combination with barium, the claim has been interpreted as being any plastic capable of being combined with a radiopaque material.

In regard to the device being configured to be pushed over a cut end of a nail; the device is inherently capable of being pushed over an end of a nail.

Claims 21-24 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Finlayson (US Patent 5,885,227).

Finlayson discloses a resilient radiopaque plastic (**Column 2, Lines 40-42**) cap (**20**) comprising a cylindrical lead-in portion (left most portion of **20**) having a first diameter; a cylindrical engagement portion having a two inner surfaces defining second (in-between portions **12c** and **12d**) and third (about portion **12d**) diameters; a protuberance found at the junction between the two engagement portion projecting radially inward; a closed end (**22**) opposite the lead-in portion; the length of the cap at least three times the inner diameter (see **Table**); the cap in combination with a metal nail (**12d**), the end of the nail being non-passivated cutting end (could cut tissue). It is clear that the very end of the cap has an outer diameter less than the outer diameter at the lead-in portion.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 8-10, and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simmons et al (US Patent 5,894,110).

Simmons et al disclose all of the claimed limitations except for the device being made specifically of polyurethane, the lead-in portion having an inner diameter of 0.080-0.092 inch, the engagement portion having an inner diameter of 0.070-0.084 inch, and a cap having 0.285-0.310 inch.

Simmons et al did disclose in Column 2, Lines 63-67 that the device is made of "a polymeric material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use polyurethane, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

As for the dimensional requirements, it is noted that such requirements are dependent upon which the cap will be placed. In the instant case, this is a wire. Therefore, for tiny wires, it would have been obvious to one having ordinary skill in the art at the time the invention was made to determine the set of dimensions since it has been held that where the general conditions of a claim are disclosed in the prior art,

Art Unit: 3733

discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-20, 27, and 28 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments with respect to claims 21-24 and 29 currently rejected under Finlayson filed May 25<sup>th</sup>, 2006 have been fully considered but they are not persuasive.

Applicant states that a metal orthopedic nail must have the stiffness to stabilize and support a fractured bone. Nowhere in applicant's specification is such structure to an orthopedic nail given. Therefore, in a completely reasonable interpretation, the examiner considered what a nail was. A relatively elongated and straight member that can be inserted into a member. The element 12d is metal as disclosed by Finlayson. Therefore, the remaining portion of the claim is orthopedic, meaning pertaining to bone. Is there not soft bone marrow within long bones? If a bone has been demineralized, is it not soft? If inserted quickly enough, would not even a relatively bendable member "nail" into a stiffer material (much like a piece of straw struck through a telephone pole after a tornado)? Merely stating a metal orthopedic nail does not impart the material properties applicant is arguing. Currently, the structure given to the language is an elongated metal object capable of being inserted into something related to bone. Further, even in the abstract, it is stated that the tip may be made stiffer or more flexible.

Applicant further states that Finlayson does not disclose the end of the nail is spaced from the lead-in portion. As clearly stated in the previous Office Action, the nail end is (12d), the lead-in portion is the left-most portion of 20. Anyone can see that 12d and the left most portion of 20 are spaced apart in the horizontal direction as shown in Figure 1. The clearance is the space between the two (about one 1/3 of the length of cap 20).

Applicant further states that end of the nail is passivated while claim 22 is claiming non-passivated. First, one cannot determine whether prior to placing cap (20) about nail (12d) that it was passivated (coated) in the first place. Regardless of whether it was coated or not prior to cap (20), the cap now is what passivates the nail (12d). Further, in regards to what makes something "passive," one could reasonably argue that the nail (12d) could have actively damaged tissue while passive within the bumper coating cap (20).

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the



Art Unit: 3733

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

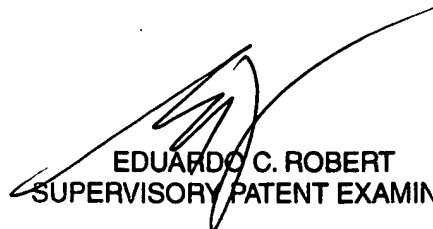
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Richard Shaffer  
August 4<sup>th</sup>, 2006



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SUPERVISORY PATENT EXAMINER